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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,952	08/17/2000	Michael S. Kinch	3220-66872	3252
26813	7590	08/09/2006		
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458				
			EXAMINER CANELLA, KAREN A	
			ART UNIT 1643	PAPER NUMBER

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/640,952		KINCH ET AL.	
	Examiner		Art Unit	
	Karen A. Canella		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1, 3-8, 11-13, 21, 23, 24, 33, 36, 37, 41-43, 45-47, 49-56, 59-66, -68, 72, 73, 75-81, 90-101 is/are allowed.
- 6) ☐ Claim(s) 9, 10, 44 and 67 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Claims 1, 3-13, 21, 23, 24, 33, 36, 37, 41-47, 49-56, 59-68, 72, 73, 75-81, 90-101 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a previous action.

Claims 9, 10, 44 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of metastatic disease in a cell population harvested from a body fluid which is blood, urine and spinal fluid does not reasonably provide enablement for a method of detecting the presence of metastatic disease in a cell population harvested from a body fluid which is plasma and saliva. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The instant claims require that fluids such as spinal fluid and saliva be used as a cellular source for metastatic cells allowing for the detection of EphA2. While it is well known in the art that patients with metastatic disease, such as metastatic breast cancer or metastatic prostate cancer, have circulating cancer cells in the blood. The art teaches complex steps for the separation of the cancer cells from the hematopoietic blood cells by density gradient centrifugation. Plasma is formed by centrifugation to separate out whole cells from blood. One of skill in the art would conclude that simple centrifugation to produce blood plasma would rid said plasma of the circulating cancer cells, and thus plasma would not be a source for metastatic cells. The art teaches that saliva is clear, viscous fluid secreted by the SALIVARY GLANDS and mucous glands of the mouth. This differs from sputum which is material coughed up from the lungs and expectorated via the mouth. Neither the specification nor any art or record provides objective evidence that an oral mouth cancer which is metastatic is the source of cells which overexpress EphA2. While one of skill in the art would know that sputum can be a source for cancerous lung cells, this is not a property of saliva. Thus, one of skill in the art would be subject to undue experimentation in order to establish a cancer type encompassed by the instant claims which would serve as a source of cells harvested from saliva.

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Claims 1, 3-8, 11-13, 21, 23, 24, 33, 36, 37, 41-43, 45-47, 49-56, 59-66, 68, 72, 73, 75-81, 90-101 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
8/6/2006


KARENA. CANELLA PH.D
PRIMARY EXAMINER

Continuation of Disposition of Claims: Claims pending in the application are 1,3-13,21,23,24,33,36,37,41-47,49-56,59-68,72,73,75-81 and 90-101.